

UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF WEST VIRGINIA  
CHARLESTON DIVISION

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**IN RE ETHICON, INC., PELVIC REPAIR  
SYSTEM PRODUCTS LIABILITY  
LITIGATION**

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This Document Applies To All Actions

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**CIVIL ACTION NO. 2:12-md-02327**

**MDL No. 2327**

Judge Joseph R. Goodwin

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**PLAINTIFFS' REPLY IN SUPPORT OF THEIR MOTION FOR  
A FINDING OF SPOILATION AND FOR SANCTIONS**

In its response to Plaintiffs' motion, Ethicon has done an about-face. Although it admitted under oath that a litigation hold applied across the TVT line since 2003, it now asserts that hold should be ignored, and mass document destruction is permissible, so long as the number of people suing the company has not yet reached a "critical mass." Ethicon further asserts that it is not "culpable" for willfully failing to monitor its employees' compliance with litigation holds, for destroying a dozen or more boxes of irreplaceable key documents from the original manufacturer, or for failing to prevent the hard drives of a number of key exiting employees from being "wiped." Finally, Ethicon argues, the Court should ignore its misconduct unless Plaintiffs can magically describe the contents of documents that they have never seen and—because of Ethicon's conduct—never will see.

Ethicon brushes off its rampant spoliation as unintentional and insignificant, but it cannot and does not dispute any of the following:

- That Ethicon removed all information from the hard drive of Renee Selman, its worldwide president for five years;
- That tens of thousands of documents that should have been produced in the custodial files of 22 witnesses could not be produced in those custodial files;

- That no documents were produced for 11% of the custodians, 500 documents or fewer were produced for 30% of custodians, and another 30% of custodians produced 1,000 documents or fewer.<sup>1</sup>
- That Ethicon was unable to produce custodial files for more than *half* of the sales representatives for the bellwether cases (that number will only continue to increase when non-bellwether cases are considered);
- That 600 pounds (a dozen or more boxes) of information from the original manufacturer of the TTV product was “lost” (or destroyed)—information that is key to this and every other TTV case;
- That Ethicon did not require its employees to use litigation hold folders and left it up to them to monitor their own compliance with the holds;
- That even by Ethicon’s timeline, information in the custody of several key employees, including Ms. Selman, was lost or destroyed *after* the duty to preserve information arose; or,
- That if outgoing employees did not take the initiative to preserve documents in their possession, then Ethicon routinely destroyed all of their information.

Instead, Ethicon throws around meaningless numbers to distract from and minimize the scope of its malfeasance. For instance, it congratulates itself for producing “millions of pages of documents.” But what Ethicon produced is not the issue; the issue is what it *lost or destroyed*. Ethicon downplays the prejudice its actions have caused by claiming that only one out of every 1,044 documents produced in discovery ever becomes an exhibit, ignoring the fact that discovery documents are not only valuable in their own right, but because they may lead to the discovery of other evidence.<sup>2</sup> Statistics like this are also meaningless without context. A single hard drive may contain 100,000 documents or, according to Ethicon’s math, 96 documents important enough to use at trial. And statistics cannot tell the full story where a higher ratio of important documents might be found in the files of key individuals like Ms. Selman.

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<sup>1</sup> See Ex. G, Mittenthal 9/25/13 Dep. at 561:2-563:20, 629:5-630:23.

<sup>2</sup> See Fed. R. Civ. P. 26(b)(1).

Most troublingly, Ethicon relies on arguments that, if accepted, would *encourage* document destruction. If Ethicon is found to have had no duty to preserve documents when lawsuits were merely “trickling” in, then companies that not only reasonably anticipate litigation, but are *already involved in litigation*, will be incentivized to destroy as much information as possible before lawsuits reach a “critical mass,” setting the stage for the widespread destruction of relevant documents. And, if Plaintiffs are denied relief because they cannot precisely identify the documents and data that are missing, companies will be incentivized to destroy as much unfavorable evidence as possible, so that no one has enough information to see what is missing.

Neither the law nor common sense support Ethicon’s positions. A company must preserve documents once it reasonably should know that they may be relevant to anticipated litigation. In 2003, Ethicon issued a litigation hold covering broad categories of documents, clearly indicating that it understood this obligation. Ethicon is legally responsible for the loss of at least tens of thousands (more likely hundreds of thousands) of documents. Even if Ethicon was merely negligent, it is “culpable” under the law. Its “blame the employees” approach does not pass muster, especially where it did nothing to monitor their compliance and where its own policies failed to require the preservation of documents. Spoliation is punishable if a reasonable jury could conclude that the missing evidence was relevant. Plaintiffs do not have to identify specific documents that were lost or destroyed. Ms. Selman’s hard drive alone surely contained relevant documents, but Ethicon destroyed them all. Then there are at least 21 other employees with missing files, boxes of missing evidence from the original manufacturer, and missing videos created by an Ethicon consultant who criticized the mesh used in the TVT.

Finally, the Court should reject Ethicon’s argument that duplicates of some spoliated evidence were produced in other files. The issue is not what was produced, but what is missing.

To demonstrate that much of the spoliated evidence has likely not been produced in some other form, Plaintiffs attach nine key documents from seven different individuals that were produced only in those individual's custodial files, and could not be located anywhere else in Ethicon's productions.<sup>3</sup> None of these important documents would have been available if the custodial files for these individuals were destroyed. Given their significance to the litigation, it is reasonable to assume that important documents like these were also contained in the custodial files of the 22 witnesses that Ethicon lost or destroyed.<sup>4</sup>

For all of these reasons, Plaintiffs deserve a more even playing field for the bellwether cases, and Ethicon should be held accountable for its conduct. The Court, therefore, should issue limited default judgments,<sup>5</sup> strike Ethicon's defenses, issue an adverse inference instruction, and order Ethicon to pay reasonable fees and expenses resulting from its spoliation.

## **ARGUMENT**

### **I. ETHICON HAD A DUTY TO PRESERVE THE SPOLIATED EVIDENCE**

#### **A. A Duty to Preserve Evidence Relating to All of Ethicon's Mesh Products Arose at Least as Early as 2003**

Throughout its brief in opposition, Ethicon acknowledges that it instituted a litigation hold related to pelvic mesh cases in 2003 and for a "handful of [other] pelvic mesh cases pending before 2008," but it argues that litigation holds in those lawsuits somehow did not trigger a preservation obligation related to the documents Plaintiffs seek in this case.<sup>6</sup> Instead, Ethicon

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<sup>3</sup> See Ex. A, Declaration of Vince Carnevale.

<sup>4</sup> See Ex. B, describing the 22 individuals for whom complete custodial files could not be produced.

<sup>5</sup> Specifically, Plaintiffs request default judgments against Ethicon in the Lewis case, and in the initial bellwether TTVT-O and Prolift cases.

<sup>6</sup> Ethicon Br. at 17-18.

argues that its “legal obligation to preserve information more broadly arose sometime between April 2008 (at the earliest), when the first litigation hold was issued in connection with one of the New Jersey-filed cases. . . and October 2010,” when the New Jersey Supreme Court ordered centralized management of the pending pelvic mesh cases.<sup>7</sup> Contrary to Ethicon’s assertion, a duty to preserve documents does not begin when litigation begins to “pick up speed,” but “when a party has notice that the evidence is relevant to litigation or. . . should [ ] know[ ] that the evidence may be relevant to future litigation.” *Silvestri v. Gen. Motors Corp.*, 271 F.3d 583, 591 (4th Cir. 2001) (quotation marks omitted).<sup>8</sup> It does not matter that the TTV cases *began* with a “trickle”; the duty to preserve arose as soon as Ethicon *reasonably anticipated litigation* and included all relevant documents in existence at that time, as well as relevant documents created thereafter. *Trevino v. Ortego*, 969 S.W.2d 950, 956 (Tex. 1998).

The test is not whether a substantial number of cases were filed, but whether Ethicon was on notice of potential litigation. *See Trevino*, 969 S.W.2d at 956 (“[I]n spoliation cases a party should be found to be on notice of potential litigation when, after viewing the totality of the circumstances, the party either actually anticipated litigation or a reasonable person in the party’s position would have anticipated litigation.”). And Ethicon cannot reasonably dispute that it was on notice of the potential litigation since at least 2003, when a lawsuit was filed relating to the defective TTV. *See Adobe Land Corp. v. Griffin, LLC*, 236 S.W. 3d 351, 359 (Tex. App. 2007) (finding that party’s filing of lawsuit related to defective herbicide—not the party’s identification of which lot was affected—required manufacturer to preserve all lot samples); *Livingston v.*

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<sup>7</sup> *Id.* at 18.

<sup>8</sup> *See also Rimkus Consulting Group, Inc. v. Cammarata*, 688 F. Supp. 2d 598, 612 (S.D. Tex. 2010); *Zubulake v. UBS Warburg, LLC*, 220 F.R.D 212 (S.D.N.Y. 2003) (“*Zubulake I*”) (duty arises when party “reasonably anticipates” litigation).

*Isuzu Motors, Ltd.*, 910 F. Supp. 1473, 1494 (D. Mont. 1995) (finding duty to preserve where, “[g]iven Isuzu’s knowledge of the Jeep CJ rollover problem in the U.S., as well as other information known industry wide involving the rollover factor in narrow truck utility vehicles, Isuzu had notice of potential relevance to this and other litigation involving their product.”).<sup>9</sup>

Particularly in the context of products liability, pharmaceutical, and medical device litigation, corporations know from experience that the first case filed is likely to be just the first of many. *See In re Pradaxa Prods. Liab. Litig.*, No. 12-md-02385, 2013 U.S. Dist. LEXIS 173674, \*3-4 (S.D. Ill. Dec. 9, 2013) (defendants could not justify narrow litigation hold when they knew that nationwide products liability cases were “imminent”). As experienced defenders of products liability litigation, Ethicon, J&J, and their in-house and outside lawyers well-understood in 2003 that the “trickle” could become a “flood.” Moreover, the litigation hold notice Ethicon itself issued—covering broad categories of documents not limited to the individual cases filed—clearly shows that Ethicon understood the scope of its responsibilities.<sup>10</sup> In this regard, it is especially telling that Ethicon has failed to offer any statements from the people who issued the litigation hold notices, or those involved in defending the then-pending cases, to support its argument that the company thought its duty to preserve was in any way limited. To the contrary: Mr. Mittenthal admitted that Ethicon was “on notice regarding litigation regarding the TVT product” *since 2003*, that no litigation holds have been removed

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<sup>9</sup> *See also Hershberger v. Ethicon Endo-Surgery, Inc.*, No. 2:10-cv-008837 (S.D.W. Va. Sept. 23, 2011), Memorandum Opinion and Order, Dkt. No. 288 (Stanley, Magistrate Judge) (finding sanctions warranted where Ethicon improperly limited discovery produced to only a specified time period, location, and product size—Ethicon should have produced all documents relating to all time periods for all product types) (attached hereto as Ex. U.).

<sup>10</sup> Ex. C, ETH.MESH.00875544.

*from 2002 to the present*, and that the holds continue to be in effect.<sup>11</sup>

**Q.** And so you would agree with me that—as the company witness that J&J is stating *at this time in 2003 that it is on notice regarding litigation regarding the TTV product*; right?

**A.** Yes<sup>12</sup>

\* \* \* \*

**Q.** And you would agree with me that Ethicon and Johnson & Johnson, at least as early as 2003, was on notice that there—that there was a need to preserve evidence relating to TTV devices in potential TTV litigation; correct?

**A.** Yes, I agree.<sup>13</sup>

\* \* \* \*

**Q.** No holds have been removed since 2002 until today, correct?

**A.** That's correct.<sup>14</sup>

That is what the holds say, that is what Ethicon said under oath before this motion was filed and that is consistent with the law.<sup>15</sup>

Nor does Ethicon offer evidence suggesting that its counsel was conducting themselves in 2003 as if the *Holley* and *Kandell* cases were the only pelvic mesh cases it was likely to face. Furthermore, if the Court accepts Ethicon's argument, it would perversely encourage defendants

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<sup>11</sup> Ex. D, Chart of Contradictory Testimony from James P. Mittenthal. *See also* Ex. I, Mittenthal 8/13/13 Dep. at 89:10-16; *id.* at 215:12-216:6; *id.* at 198:9-11.

<sup>12</sup> Ex. I, Mittenthal 8/13/13 Dep. at 89:10-16

<sup>13</sup> *Id.* at 215:12-216:6

<sup>14</sup> *Id.* at 198:9-11. Indeed, Mittenthal agreed that even mesh litigation involving manufacturers other than Ethicon could put the company on notice that it needed to preserve mesh-related information. *See id.* at 100:3-9.

<sup>15</sup> Ex. E, Mittenthal 5/14/13 Dep. at 271:18-22.

to destroy damaging documents not directly connected with specific litigation as soon as they are sued to sanitize their records before other cases are filed.<sup>16</sup> *See Goodman v. Praxair Servs.*, 632 F. Supp. 2d 494, 518 n.12 (D. Md. 2009) (argument that accused spoliator maintained “relevant” information rang hollow: ultimate decision of what is relevant is “not determined by a party’s subjective assessment filtered through its own perception of self-interest.”).

Not only does the broad scope of the litigation hold Ethicon issued in 2003 when the first mesh product liability cases were filed against it severely undercut the argument that its duty to preserve in connection with those cases was more limited than the duty in this litigation, but the cases Ethicon cites in support of the notion that its feeble efforts were somehow “proportional” to the seriousness of the litigation it then faced (*see Ethicon Br.* at 16-17) do not help it. The court’s reasoning in *In re Pradaxa (Dabigatran Etexilate) Products Liability Litig.*, for example, supports Plaintiffs’ position, as the defendant in that case *agreed* that its duty to preserve arose no later than the date the first post-launch product liability case was filed against it. 2013 U.S. Dist. LEXIS 137235, \*8, 27-33. The dispute in *Pradaxa* centered on whether a duty to preserve arose in connection with two earlier cases involving patients who took the defendant’s drug as part of clinical trials conducted before FDA approval. *Id.* at \*36. Finding itself with this unique fact pattern, and noting that the FDA subsequently approved labeling information including warnings relating to the injuries suffered in the clinical trials, the court held the earlier litigation did not reasonably give the defendant a reason to anticipate post-launch, post-warning litigation. *Id.* at \*37-38.

And in *Rimkus*, the court noted that “[i]t can be difficult to draw bright-line distinctions between acceptable and unacceptable conduct,” stating not only that efforts must be proportional

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<sup>16</sup> Ex. D, p. 6, notice of other mesh litigation would have put Ethicon on notice that it needed “to be preserving mesh-related information.”

to the case, but also “*consistent with clearly established applicable standards.*” 688 F. Supp. 2d 598 (emphasis added). As described in more detail below, Ethicon’s preservation efforts have been so *inconsistent* with applicable standards that a test permitting a bright-line determination is unnecessary—it is not even a close case.

**B. Ethicon’s Duty to Preserve Must as Least Coincide with the Period of Time for Which it Claims Work Product Protection**

In fact, Ethicon anticipated litigation *well* before 2008 by asserting work product privilege for a number of earlier documents, an inconsistency it makes no attempt to reconcile. For a party to invoke the work product doctrine, “[t]he document must be prepared because of the prospect of litigation when the preparer faces an actual claim or a potential claim following an actual event or series of events that reasonably could result in litigation.” *Nat'l Union Fire Ins. Co. of Pittsburgh, Pa. v. Murray Sheet Metal Co.*, 967 F.2d 980, 984 (4th Cir. 1992). Thus, work product protection does not attach until the party “reasonably anticipate[s] litigation.” *Chambers v. Allstate Ins. Co.*, 206 F.R.D. 579, 586 (S.D.W. Va. 2002); *accord William A. Gross Const., Assocs., v. Am. Mfrs. Mut. Ins. Co.*, 262 F.R.D. 354, 362 (S.D.N.Y. 2009).

Because the legal standard—reasonable anticipation of litigation—is the same for both the work product protection and for triggering a duty to preserve documents, a party who withholds documents based on work product grounds is deemed to have a corresponding duty to preserve documents *at least* as of the date of the *earliest* document that it claims was prepared in anticipation of litigation. *Sinai v. State Univ. of N.Y. at Farmingdale*, No. CV 09-407, 2010 U.S. Dist. LEXIS 82562, \*16-17 (E.D.N.Y. Aug. 10, 2010) (“If it was reasonably foreseeable for work product purposes. . . it was reasonably foreseeable for duty to preserve purposes”).<sup>17</sup>

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<sup>17</sup> See also *Sanofi-Aventis Deutschland GmbH v. Glenmark Pham. Inc., USA*, No. 07-CV-5855, 2010 U.S. Dist. LEXIS 65323, \*14-15 (D.N.J. Jul. 1, 2010) (“duty to impose a litigation hold and to institute legal monitoring for purposes of compliance arose *no later than* the date of the

Ethicon has claimed work product protection for these documents, among many others:

<b>Date</b>	<b>Priv. Log #</b>	<b>Subject and/or Privilege Narrative</b>
5/7/2003	PL01552	Letter from Federico Fontana* to client consultant reflecting Federico Fontana's* legal analysis and <i>work product regarding potential TVT Litigation</i>
12/17/2003	PL18228	Attention GYNECARE Associates - Must Read- Updated TVT Hold Notice! Email from client employee to client employees copying client employees reflecting Lisbeth Warren's* legal analysis and <i>work product regarding Pelvic Mesh litigation</i> <sup>18</sup>

Thus, by Ethicon's own admission, it actually (and reasonably) anticipated the present litigation *at least as early as May 7, 2003*, shortly after the second mesh case was filed, a fact confirmed by the issuance of its first litigation hold a few days later on May 22, 2003.<sup>19</sup> Accordingly, Ethicon's duty to preserve evidence existed at least as early as May 7, 2003. Because Ethicon failed to prevent the loss of relevant evidence after it *actually* anticipated litigation, its culpability is *greater* than if it had merely failed to reasonably anticipate litigation.

Not only does the broad scope of the litigation hold Ethicon issued in 2003 when the first mesh product liability cases were filed against it severely undercut the argument that its duty to

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earliest document as to which work product protection was claimed and its systematic destruction of documents after that date warranted an adverse inference); *Anderson v. Sotheby's Inc. Severance Plan*, 04 CIV. 8180 (SAS), 2005 U.S. Dist. LEXIS 23517, \*15-16 (S.D.N.Y. Oct. 11, 2005) ("because the Administrator claimed that it reasonably anticipated litigation as of July 6, 2004 [for work product purposes, its] duty to preserve the documents arose as of that date"); *PacifiCorp v. Nw. Pipeline GP*, 879 F. Supp. 2d 1171, 1189-90 (D. Or. 2012) (plaintiff was judicially estopped from taking the position that documents were entitled to work product protection before the plaintiff had a duty to preserve evidence); *Samsung Electronics Co., Ltd. v. Rambus, Inc.*, 439 F. Supp. 2d 524, 542-43 (E.D. Va. 2006), *vacated on grounds of mootness*, 523 F.3d 1374 (Fed. Cir. 2008) (standard for work product protection applied to determine when a party anticipated litigation for purposes of its duty to preserve relevant evidence).

<sup>18</sup> Ethicon Privilege Log (emphasis added).

<sup>19</sup> Ex. C, ETH.MESH.00875544.

preserve in connection with those cases was more limited than the duty in this litigation, but the cases Ethicon cites in support of the notion that its feeble efforts were somehow “proportional” to the seriousness of the litigation it then faced (*see Ethicon Br.* at 16-17) do not help it. The court’s reasoning in *In re Pradaxa (Dabigatran Etexilate) Products Liability Litig.*, for example, supports Plaintiffs’ position, as the defendant in that case *agreed* that its duty to preserve arose no later than the date the first post-launch product liability case was filed against it. MDL No. 2385, 2013 U.S. Dist. LEXIS 137235, \*8, 27-33 (S.D. Ill. Sept. 25, 2013). The dispute in *Pradaxa* centered on whether a duty to preserve arose in connection with two earlier cases involving patients who took the defendant’s drug as part of clinical trials conducted before FDA approval. *Id.* at \*36. Finding itself with this unique fact pattern, and noting that the FDA subsequently approved labeling information including warnings relating to the injuries suffered in the clinical trials, the court held the earlier litigation did not reasonably give the defendant a reason to anticipate post-launch, post-warning litigation. *Id.* at \*37-38.

And in *Rimkus*, the court noted that “[i]t can be difficult to draw bright-line distinctions between acceptable and unacceptable conduct,” stating not only that efforts must be proportional to the case, but also “*consistent with clearly established applicable standards.*” 688 F. Supp. 2d 598. As described in more detail below, Ethicon’s preservation efforts have been *inconsistent* with applicable standards that a test permitting a bright-line determination is unnecessary—it is not even a close case.

## **II. THE RECENT SEA CHANGE IN ETHICON’S PRESERVATION EFFORTS ONLY HIGHLIGHTS THE DEFICIENCY OF ITS EARLIER EFFORTS**

Ethicon chiefly relies upon the Declaration of James Mittenthal to support its arguments that it did not engage in spoliation. Setting aside the fact that Mr. Mittenthal’s opinions should be disregarded by the Court because of the numerous hearsay problems and inconsistencies that

will be addressed in this Brief, his opinions still provide no basis to show that Ethicon correctly preserved documents during the relevant time period. Mr. Mittenthal disputes that the Corrective and Preventative Action (“CAPA”) opened by Ethicon in January 2007 evinces Ethicon’s failure to preserve documents (a failure the company noted in an internal audit as early as 2002). His assertions are based on his own “fact-finding,” but he fails to explain what facts he relies on.<sup>20</sup>

In fact, Mittenthal had never even *heard* of the CAPA until Plaintiffs’ counsel raised it with him at his deposition; his lawyers at the time acted to have him disavow it and he later admitted that this was relevant to the matters raised by this motion. Although Mr. Mittenthal now acknowledges that the 2007 CAPA was important to understand, and something he would want to learn of during his fact finding, he was not provided any information about this CAPA until *after* he was questioned about it by Plaintiffs’ counsel during his May 14, 2013 deposition.<sup>21</sup> Regardless, he is playing a game of semantics in asserting that the CAPA was not based on a failure to “preserve” documents. The 2002 internal audit that prompted the CAPA cited Ethicon for “not having a formal Records Management Program.”<sup>22</sup> Without a formal mechanism for managing documents, Ethicon could not have ensured that documents were preserved. That concept is further supported by a consultant’s 2006 audit, which concluded that Ethicon’s “current paper-based method of document management and retention has become untenable.”<sup>23</sup> The CAPA was opened in 2007 because it was found that “Ethicon c[ould] not

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<sup>20</sup> Mittenthal Decl. at ¶ 59.

<sup>21</sup> Ex. E, Mittenthal 5/14/13 Dep. at 270:18-273:1

<sup>22</sup> Ex. F, CAPA070011 Summary Report, at ETH.MESH.09479228; Ex. G, Mittenthal 09/25/13 Dep. at 464:23-466:1.

<sup>23</sup> Ex. H, ETH.MESH.04611734, *Executive Summary: Medical, Regulatory and Quality Systems Diagnostic*, at p. 9, ¶ 8.

appropriately provide all relevant documents *in case of litigation* or inspection.”<sup>24</sup> Although Mr. Mittenthal attempts to downplay its significance, he admitted that Ethicon “undertook a CAPA as being the most effective means to put procedures and standards in place by which that adherence could be maintained.”<sup>25</sup> The CAPA was not closed until 2009.

The Court should reject Ethicon’s efforts to downplay the importance of the CAPA. The documents show that Ethicon had no formal document management program, and yet it took *Plaintiffs* complaining about the lack of documents for Ethicon to even to begin taking corrective action. Just like the audit and CAPA showed, Ethicon’s system for document management *and retention* was “untenable,” and Ethicon was not able to produce all relevant documents for litigation. This train was coming before Plaintiffs had any inkling of it, but Ethicon knew all along. Yet, Mr. Mittenthal would like for the Court to take his word—as an outsider paid by Ethicon to investigate the situation after-the-fact—that none of these problems had anything to do with document retention. The Court should decline this invitation. Mr. Mittenthal also argues that the CAPA was not specific to pelvic mesh products,<sup>26</sup> which is wholly irrelevant. The audits make clear that Ethicon was not managing *any* of its documents properly.<sup>27</sup>

### **III. ETHICON ACTED WITH A CULPABLE MIND**

#### **A. Ethicon’s Utter Failure to Monitor and Ensure Compliance with Its Litigation Holds Was, at a Minimum, Gross Negligence**

Ethicon argues that a party does not act with a culpable mind where “an effective

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<sup>24</sup> Ex. F, CAPA070011 Summary Report, at ETH.MESH.09479227 (emphasis added).

<sup>25</sup> Ex. G, Mittenthal 09/25/13 Dep. at 386:8-23.

<sup>26</sup> Mittenthal Decl. at ¶ 59.

<sup>27</sup> Not only did the CAPA summary express concern that Ethicon was unable to produce documents *for litigation*,<sup>27</sup> but it also noted that Ethicon was “[u]nable to carry out [a] Records Cleanout due to legal restriction.” Ex. F, ETH.MESH.09479233-34

litigation hold policy [is] in place.”<sup>28</sup> As Mr. Mittenthal himself admitted, however, litigation holds are only effective if followed, and it is a company’s responsibility to ensure that its procedures are in fact being followed.<sup>29</sup> Courts overwhelmingly agree.<sup>30</sup> A party’s obligations “do not end with the implementation of a ‘litigation hold’—to the contrary, that’s only the beginning.” *Zubulake v. UBS Warburg LLC* (“*Zubulake II*”), 229 F.R.D. 422, 432 (E.D.N.Y. 2003).

For many years, however, Ethicon and its counsel contented themselves with issuing litigation holds to its district managers—who were then given broad discretion over who should receive them and how documents should be preserved. Ethicon offers no evidence that it ever did anything to determine whether anyone was actually complying with its holds. Although Mr. Mittenthal stated at his deposition that “the company [i]s responsible for the actions of its employees,”<sup>31</sup> his declaration simply blames individual employees for failing to follow the

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<sup>28</sup> Ethicon Br. at 19 (*citing Danny Lynn elec. v. Veolia Es Solid Wast*, No. 2:09CV192-MHT (WO), 2012 U.S. Dist. LEXIS 31685, \*10-11 (M.D. Ala. Mar. 9, 2012)).

<sup>29</sup> See Ex. I, Mittenthal 8/13/13 Dep. at 213:9-17; Ex. G, Mittenthal 9/25/13 Dep. at 493:11-16.

<sup>30</sup> See, e.g., *Zubulake II*, 229 F.R.D. at 432-33 (“Counsel must take affirmative steps to monitor compliance . . . [and] is under a continuing duty to ensure preservation.”); *Fitzpatrick v. Am. Int’l Group, Inc.*, No. 10 Civ. 142 (MHD), 2013 U.S. Dist. LEXIS 77741, \*31-32 (S.D.N.Y. May 29, 2013) (“[T]he party—and its counsel—must monitor the party’s compliance with the litigation hold, ensuring that all relevant actors understand the policy and are implementing it faithfully.”); *Mastr Adjustable Rate Mortgages Trust 2006-OA2 v. UBS Real Estate Secs. Inc.*, No. 12 Civ. 7322 (HB) (JCF), 2013 U.S. Dist. LEXIS 152441, \*21 (S.D.N.Y. Oct. 23, 2013) (“A litigation hold is not, alone, sufficient; instead compliance must be monitored.”); *U.S. v. Comm. Health Sys., Inc.*, No. 05-279 WJ/ACT, 2012 U.S. Dist. LEXIS 144892, \*13 (D. N.M. Oct. 3, 2012) (“It is not sufficient ‘to notify all employees of a litigation hold and expect that the party will then retain and produce all relevant information.’”).

<sup>31</sup> See Ex. G, Mittenthal 9/25/13 Dep. at 599:21-25.

policies and procedures that Ethicon did nothing to enforce.<sup>32</sup>

Where litigants rely on such a “trickle down” approach, courts have found their preservation efforts “woefully inadequate” and “beyond mere negligence,” even if the absence of bad faith or willful misconduct. *See, e.g., U.S. v. Comm. Health Sys. Inc. (“Baker”)*, No. 05-279, 2012 U.S. Dist. LEXIS 146865, \*35, 40 (D.N.M. Aug. 31, 2012) (report and recommendation), *adopted by, objections overruled by*, 2012 U.S. Dist. LEXIS 144892 (D.N.M. Oct. 3, 2012). *See also United Factory Furniture Corp. v. Alterwitz*, No. 2:12-cv-00059-KJD-VCF, 2012 U.S. Dist. LEXIS 48795, \*8 (D. Nev. Apr. 6, 2012) (failure to affirmatively monitor compliance with a litigation hold “constitutes gross negligence for sanctions purposes, because it is likely to result in destruction of relevant information”).

In *Baker*, the defendant in a *qui tam* action sought spoliation sanctions against the U.S. Government for improperly implementing a litigation hold. The attorney in charge of the hold sent preservation notices to directors or other high-level agency officials instructing them to make sure the notice was distributed to all individuals who might have relevant information. *Id.* at \*25-27. The court noted that the attorney “assumed that [the government agencies] would follow the written instructions she gave them about the litigation hold” and “did not designate such individuals herself[, but instead] assumed her contacts would ensure that the proper parties

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<sup>32</sup> *See, e.g.*, Mittenthal Decl. at ¶ 86 (“any losses of data were attributable to some type of misunderstanding by an employee and/or a miscommunication between a departing employee and his or her manager”). Although cited authority notes that, even after a litigation hold is issued, “the key players should be periodically reminded that the preservation duty is still in place,” Mr. Mittenthal also testified that, at least until April 30, 2007, Ethicon sent its employees no reminders, but merely directed them to a website where they could ostensibly research which notices affected them. Ex. I, Mittenthal 8/13/13 Dep. at 117-18.

would be instructed.” *Id.* at \*26-27 (emphasis in original).<sup>33</sup> Additionally, although a written policy called for the business component for a departing employee to notify the Office of Information Services that it should halt the otherwise automatic destruction of the employees’ files, the policy was not complied with and documents for key individuals were destroyed when they retired from the company. *Id.* at \*28-30.<sup>34</sup> Citing the “lackadaisical attitude with which the Government approached its ongoing duty to insure that the litigation hold was adequate and being properly monitored,” *id.* at \*34 n.5, the court ordered, *inter alia*, the production of a number of documents previously withheld as privileged and monetary sanctions, *id.* at \*52-54.

Ethicon also *encouraged* its employees to stop creating documents in the normal course of business,<sup>35</sup> a practice evidenced by some of the training documents it provided to its employees instructing them on “careful communications”<sup>36</sup> and discouraging them from putting “anything in an e-mail.”<sup>37</sup> Ethicon also asked key company employees to provide opinions “in

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<sup>33</sup> Mr. Mittenthal described Ethicon’s employment of similar procedures, by which district managers were ultimately responsible for making sure their employees with relevant information received litigation hold notices. *See Ex. I*, Mittenthal 8/8/13 Dep. at 115:9-116:2.

<sup>34</sup> *See Ex. G*, Mittenthal 9/25/13 Dep. at 347:14-353:22 (describing similar failures in which the IT department was not notified in time to preserve relevant information from departing employees).

<sup>35</sup> Ethicon also utterly failed to keep backup tapes, when such a practice is normal and customary for businesses to do. *See United States v. Duronio*, No. 02-933 (JAG), 2006 U.S. Dist. LEXIS 32313, \*5 n.7 (D.N.J. May 23, 2006) (describing back-up tapes, different from mirror images of a computer hard drive, as “usually taken during the ordinary course of business”). *See also Zubulake II*, 229 F.R.D. at 439 (once a litigation hold is in place, attorneys “must also call for employees to produce copies of relevant electronic evidence, *and must arrange for the segregation and safeguarding of any archival media* (e.g., backup tapes) that the party has a duty to preserve.” (emphasis added)). When internal audits made clear that Ethicon had document maintenance and retention issues, this certainly should have been made a priority.

<sup>36</sup> *Ex. J*, ETH.MESH.00619152.

<sup>37</sup> *Ex. K*, ETH.MESH.02087831.

person, or by phone,” warned them not to put any opinions in writing concerning a paper it did not like: “Polypropylene as a reinforcement in pelvic surgery is not inert: comparative analysis of 100 explants,”<sup>38</sup> and sternly cautioned them to “NOT COMMUNICATE ANY OPINIONS VIA E-MAIL.”<sup>39</sup> Employees were also warned not to discuss the “rate of complaints for erosions in Prolift+M” via e-mail, either.<sup>40</sup> Such warnings, given when litigation had already commenced, were likely to send a NOT-SO-SUBTLE message that—notwithstanding any formal litigation hold—Ethicon would prefer not to have to produce embarrassing documents in litigation. In an atmosphere where the preservation of documents depended on the discretion of poorly-supervised and instructed individual employees, Ethicon’s argument that it lacks culpability falls flat.

Spoliation sanctions are proper, here, because they are meant to prevent spoliators from benefiting from their wrongdoing, and “it makes little sense to confine promotion of that remedial purpose to cases involving only outrageous culpability, where the party victimized by the spoliation is prejudiced irrespective of whether the spoliator acted with intent or gross negligence.” *Reilly v. Natwest Mkts. Group Inc.*, 181 F.3d 253, 267-68 (2d Cir. 1999). *See also Baker*, 2012 U.S. Dist. LEXIS 146865, at \*52 (“There is no point in requiring a party to preserve evidence and to instigate a timely and adequate litigation hold if there are no consequences

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<sup>38</sup> Ex. M, ETH.MESH.03750969.

<sup>39</sup> *Id.* Ethicon also cautioned its employees to “[b]e very cognizant of what you are communicating electronically as any and all forms of communications can be discoverable in a court of law.” Ex. L, ETH.MESH.07946455, 65. Aware of the discoverability of existing communications, Ethicon also cautioned its employees via “careful communication” training that “E-mail is forever” and “Every communication matters. Everything is a document. Everything is discoverable.” Ex. N, ETH.MESH.0114865. Everything, that is, except the tens or hundreds of thousands of spoliated documents at issue here.

<sup>40</sup> *See* Ex. V, ETH.MESH.00594767.

unless the failure to do so was intentional, wilful [sic], or in bad faith.”).

#### **IV. THE COURT SHOULD DISREGARD ETHICON’S SELF-SERVING DECLARATIONS**

Underlying Ethicon’s arguments are facts asserted and conclusions drawn in the declarations of James Mittenthal and Pamela Downs, each hired by Ethicon to perform investigations on its behalf for purposes of this litigation. However, the Court should place little value on these self-serving declarations, as it is well-established that the results of such internal company investigations are inadmissible, both because they are based on inadmissible hearsay and because they contain inadmissible opinions. *See, e.g., Certain Underwriters at Lloyd’s, London v. Sinkovich*, 232 F.3d 200, 202-06 (4th Cir. 2000) (district court erred in admitting investigative report under the business record exception and by admitting improper testimony from investigator).<sup>41</sup> Additionally, and most egregiously, statements made in Mr. Mittenthal’s declaration directly contradict his deposition testimony in a number of respects (demonstrated by the attached Exhibit D).<sup>42</sup> *See Flores v. Phoenix Group Metals, LLC*, No. H-10-5143, 2013 U.S. Dist. LEXIS 45829, \* 16 n.55 (S.D. Tex. Feb. 14, 2013) (court struck affidavit that “call[ed] into question its sincerity” when it “blatantly contradict[ed] prior testimony”).

##### **A. The Declarations Are Based on Hearsay Statements.**

Beginning in 2011, Ethicon hired Mr. Mittenthal to examine the company’s records management and retention systems to provide testimony as a corporate representative in connection with this litigation. He states that, in connection with his review, he interviewed over 100 different individuals—without identifying them by name. In approximately April 2013, he

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<sup>41</sup> Even if this corporate internal investigation satisfied some exception to the hearsay rule, it should nevertheless be excluded. *Castelluccio v. Int’l Bus. Machines Corp.*, 3:09CV1145 TPS, 2013 WL 6842895 (D. Conn. Dec. 23, 2013).

<sup>42</sup> *See* Ex. D, Chart of Contradictory Testimony from James P. Mittenthal.

was asked to examine the issues related to specific custodians who had been found to have few or no documents in their custodial files. Mittenthal declares that he spoke to current and former employees, reviewed portions of deposition testimony, and studied documents regarding compliance with records retention procedures.<sup>43</sup> Mittenthal does not identify with any specificity the documents he reviewed, and only four documents are attached to his declaration.

Ethicon does not offer Mr. Mittenthal as an expert and repeatedly objected to questions at his deposition that “called for expert opinion.”<sup>44</sup> Based on what he was told and what he read, however, he purports to offer a host of opinions to the effect that Ethicon’s actions were inadvertent or unintentional and that the resulting loss of evidence did not prejudice Plaintiffs.<sup>45</sup>

Mittenthal transparently bases his conclusions on nothing but hearsay: “statement[s] that: (1) the declarant does not make while testifying at the current trial or hearing and (2) a party offers in evidence to prove the truth of the matter asserted.” Fed. R. Evid. 801(c). His accounts are based entirely on out-of-court statements offered by Ethicon<sup>46</sup> and—if the Court considers

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<sup>43</sup> Mittenthal Decl. at ¶¶ 4-7.

<sup>44</sup> Neither can offer conclusions as to whether Defendants acted with a culpable state of mind—neither has any personal knowledge of the facts and neither has been offered as an expert. Therefore, “[a]s a lay, not expert, witness, [each] lacked the personal knowledge necessary to express the opinions that he [or she] did.” *Underwriters at Lloyd’s*, 232 F.3d at 204; *see also Connell v. Bank of Boston*, 924 F.2d 1169, 1177-78, n.7 (1st Cir. 1991) (testimony by lay witness as to personal opinion on the ultimate issue in the case contravened Fed. R. Evid. 701).

<sup>45</sup> Similarly, Pamela Downs was engaged by Ethicon in 2013 to investigate the facts concerning certain documents maintained by Ethicon outside of the United States, including documents provided to Ethicon by MedScand. She claims to have “interviewed over 25 Ethicon employees and reviewed numerous documents,” without identifying them. Downs Decl. at ¶¶ 4-5. Based on her investigation, she purports to testify to her “understanding,” (based on what she was told and documents she reviewed) and to draw conclusions based on what she has been “unable to determine.” *Id.* at ¶ 10. Like Mittenthal, she does not claim to have any personal knowledge of the facts and Ethicon does not offer her as an expert.

<sup>46</sup> Mittenthal’s and Downs’ reports of their investigations furthermore do not qualify as “business records.” *See* Fed. R. Evid. 803(6). *Paddack v. Dave Christensen, Inc.*, 745 F.2d 1254, 1258-59

them at all—should be given little weight for purposes of this motion.

In addition, testimony as to facts must generally be based on the witness's personal knowledge. *Howley v. Town of Stratford*, 217 F.3d 141, 155 (2d Cir. 2000). Opinions arising from internal investigations (which are generally based on hearsay and not on personal knowledge) are considered inadmissible and should be afforded no weight.<sup>47</sup> Mittenthal does not have personal knowledge of the events as to which he testifies, but bases his conclusions on the unsworn hearsay statements of witnesses who may have a motivation to protect themselves.<sup>48</sup>

#### **V. THE PROPOSED SANCTIONS ARE REASONABLE AND FAIR**

When a party either fails to preserve or destroys potential evidence in connection with foreseeable litigation, it can be deemed to have engaged in the spoliation of evidence, and a trial court may use its inherent power to impose an appropriate sanction.<sup>49</sup> See *Silvestri*, 271 F.3d at 590. Where a party to litigation has spoliated evidence, the court should impose sanctions that

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(9th Cir. 1984); *Underwriters at Lloyd's*, 232 F.3d at 205. Nor are the contents of their declarations admissible as reports or records of public officials or agencies (Fed. R. Evid. 803(8)(A)(iii)) or voluminous writings (Fed. R. Evid. 1006; *Paddock*, 745 F.2d at 1259–60; *S.E.C. v. Price Waterhouse*, 797 F. Supp. 1217, 1220 n.8 (S.D.N.Y. 1992)).

<sup>47</sup> See, e.g., *Paddock*, 745 F.2d 1254, 1258 (9th Cir. 1984) (audit report prepared in response to suspicion of irregularities was inadmissible hearsay); *United States v. Reyes*, 239 F.R.D. 591, 600 (N.D. Cal. 2006) (internal investigation materials were hearsay and “hearsay upon hearsay”).

<sup>48</sup> This is compounded by the fact that Mittenthal and Downs often rely on things third parties were told by *fourth parties*, thereby adding an additional level of hearsay. See *Rodriguez v. Bd. of Trs. of the Laredo Indep. Sch. Dist.*, 143 F. Supp.2d 727, 739-40 (S.D. Tex. 2001) (memorandum containing statements from others about which author had no personal knowledge was hearsay); *Hearn v. Greyhound Lines, Inc.*, No. 3:97-CV-1483-R, 1998 U.S. Dist. LEXIS 11375, \*15-16 (N. D. Tex. July 21, 1998) (statements in declaration constituting hearsay within hearsay “stricken based on Federal Rule of Evidence 805”), *aff'd* 176 F.3d 479 (5th Cir. 1999).

<sup>49</sup> Plaintiffs are not proposing a specific “one-size-fits-all” instruction to be given in every case. The cases in the MDL involve different facts, claims, and laws. But as an example, the Court could permit the jury in a given case to presume that the Plaintiffs would have been able to produce additional evidence on certain topics, if not for Ethicon’s spoliation. Such an instruction would not say anything about Ethicon’s state of mind.

serve the twin purposes of “leveling the evidentiary playing field and . . . sanctioning the improper conduct.” *Vodusek v. Bayliner Marine Corp.*, 71 F.3d 148, 156 (4th Cir. 1995).

**A. A Default Judgment is Justified Because Ethicon Acted in Bad Faith and Caused Extraordinary Prejudice**

A default judgment, the “ultimate sanction for spoliation” is “justified” if either (1) the spoliator’s conduct involved “bad faith or ‘like action’” or (2) the prejudice to the plaintiff was “extraordinary.” *Silvestri*, 271 F.3d at 593; *see also Suntrust Mortgage, Inc. v. United Guar. Residential Ins. Co. of N. Carolina*, 508 F. App’x 243, 254-55 (4th Cir. 2013). As a sanction for spoliation, dismissal or default has been ordered in a variety of situations.<sup>50</sup>

Ethicon’s misconduct was tantamount to bad faith. The 2002 audit shows that the company knew its document preservation procedures were inadequate to preserve documents for litigation discovery purposes. It also knew that it had a duty to preserve documents relevant to the mesh litigation at least as early as May 2003 when it first claimed work product protection and issued its first hold notice in response to actual litigation. The 2007 CAPA shows that Ethicon ignored its document preservation responsibilities by neglecting the problem for an unbelievable *seven years* (the CAPA remained outstanding until 2009). It offers no admissible

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<sup>50</sup> See, e.g., *Carlucci v. Piper Aircraft Corp.*, 102 F.R.D. 472, 486 (S.D. Fla. 1984) (entry of default judgment against defendant where destruction of documents was intentional); *Teletron, Inc. v. Overhead Door Corp.*, 116 F.R.D. 107, 110 (S.D. Fla. 1987) (default judgment granted where willful document destruction resulted in irretrievable loss of evidence); *Wm. T. Thompson Co. v. Gen. Nutrition Corp., Inc.*, 593 F. Supp. 1443, 1455-56 (C.D. Cal. 1984) (entry of default judgment where a corporate defendant had “knowingly and purposefully” permitted its employees to destroy key documents and records, thereby depriving the plaintiff of access to objective evidence needed to build its case against the defendant); *Computer Assoc. Int’l, Inc. v. Am. Fundware, Inc.*, 133 F.R.D. 166, 170 (D. Colo. 1990) (default judgment was the only appropriate remedy against defendant who destroyed all copies of its source code despite a duty to preserve it); *Century ML-Cable Corp. v. Carrillo*, 43 F. Supp. 2d 176 185 (D.P.R. 1998) (defendant’s willful destruction of his laptop and business records justified entry of default judgment against him and order to pay attorneys’ fees and costs); *Marrocco v. Gen. Motors Corp.*, 966 F.2d 220, 224-25 (7th Cir. 1992) (dismissing one claim in consolidated appeal; entering default judgment against defendant on the other claim).

evidence that it made any effort to monitor compliance with or enforce its “litigation holds.” Indeed, it appears that Ethicon did not take any serious steps to address the inadequacies of its document management problems until “the past year or so. . . in response to issues identified in connection with this MDL.”<sup>51</sup> As such, Ethicon may fairly be said to have been guilty of a “callous disregard” of its responsibilities amounting to bad faith – warranting the severest sanction available to the Court. *See Nat'l Hockey League v. Metro. Hockey Club, Inc.*, 427 U.S. 639, 643 (1976) (district court did not abuse its discretion in dismissing complaint as a sanction).

A default judgment is appropriate because Ethicon’s egregious misconduct severely prejudiced Plaintiffs ability to successfully prosecute their claims. For instance, due to the destruction of the 12 cases from Medscand, Plaintiffs have no access to patient-level data from the Ulmsten studies, which an Ethicon employee described as the “cornerstone” of Ethicon’s marketing program.<sup>52</sup> Ethicon also has not produced the original Risk Assessment for the TVT device,<sup>53</sup> the Medscand Design History File, or the Technical File. Rather, in response to that specific request, it produced a few documents from what it termed a “joint” Ethicon-Medscand file, stating it would “continu[e] to investigate whether there is a DHF solely by Medscand.”<sup>54</sup>

Without this information, Plaintiffs are unable to assess what the original studies regarding the products at issue showed. Such information is particularly relevant to their claims

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<sup>51</sup> Mittenthal Decl. ¶ 52.

<sup>52</sup> Ex. O, Rick Isenberg 11/06/13 Dep. (rough) at 421:13-19. Ethicon has not even produced the manifests from the 12 missing cases of documents from Medscand—11 of which Ethicon destroyed itself, and one of which was destroyed by fire. Ex. P, Benjamin Watson 12/18/13 letter to Andrew Faes.<sup>52</sup>

<sup>53</sup> *Id.*

<sup>54</sup> *See* Ex. Q, Benjamin Watson 12-20-13 letter to Roger Cameron; *see also* Ex. R, Roger Cameron 11-04-13 letter to Benjamin Watson.

of design defect, negligence, and failure to warn, because it bears on whether Ethicon was putting safe products on the market, and relatedly, what it knew about the safety of its products. For instance, if the Design History File or the patient-level data revealed a particular design flaw or adverse consequence involving one or more products, this information would bear directly on whether the product was unreasonably dangerous, on whether Ethicon acted reasonably in marketing and selling the product, and on whether Ethicon warnings were adequate.

Finally, a severe sanction is particularly appropriate in this case to ““to deter those who might be tempted to such conduct in the absence of such a deterrent.”” *In re Ethicon, Inc. Pelvic Repair System Prod. Liab. Litig. (Saucedo v. Ethicon, Inc.)*, 2:13-cv-20805, Order entered Dec. 20, 2013 [Dkt. 10] at 4 (S.D.W. Va. 2013), quoting *Nat'l Hockey League*, 427 U.S. at 643.

#### **B. Adverse Jury Instructions Are Proper Given Ethicon’s Level of Culpability**

Ethicon’s misrepresents the state of Fourth Circuit law by claiming that such an instruction “requires a showing that the party knew the evidence was relevant to some issue at trial and that his *willful conduct* resulted in its loss or destruction.”<sup>55</sup> That statement traces back to the Fourth Circuit’s opinion in *Vodusek*, 71 F.3d at 156. Ethicon conveniently fails to note that the Fourth Circuit was reciting the standard for drawing “[a]n adverse inference about a party’s consciousness of the weakness of his case.” *Id.* (emphasis added). Thus, a showing of willfulness would be required to support an instruction that Ethicon destroyed evidence *because* it knew that doing so would aid its case. To be clear, Plaintiffs have established willfulness, and such an instruction would be appropriate. But this Court may also submit a more general adverse inference instruction even if it finds that the Defendants were merely negligent.

The Fourth Circuit rejected the argument that either bad faith or willful conduct was

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<sup>55</sup> Ethicon Br. at 31 (emphasis added).

necessary to a finding of spoliation, explaining: “the trial court has broad discretion to permit a jury to draw adverse inferences from a party’s failure to present evidence, the loss of evidence, or the destruction of evidence. While a finding of bad faith suffices to permit such an inference, it is not always necessary.” *Id.* In *Vodusek*, the Plaintiffs damaged a boat while investigating why it had caught fire. The defendants asked for a spoliation instruction, arguing that they had lost access to relevant evidence. *Id.* at 155. The Fourth Circuit concluded that even in the absence of bad faith, the lost evidence justified a spoliation instruction. *Id.* at 156-57.

Thus, adverse inference instructions are appropriate in response to negligent spoliation because a primary goal of spoliation sanctions is to restore the prejudiced party to the position it would have been in had the evidence been preserved. Laura A. Adams, *Reconsidering Spoliation Doctrine Through the Lens of Tort Law*, 85 Temp. L. Rev. 137, 150-51 (2012). As one court has explained, the adverse inference “sanction should be available even for the negligent destruction of documents if that is necessary to further the remedial purpose of the inference.” *Turner v. Hudson Transit Lines, Inc.*, 142 F.R.D. 68, 75 (S.D.N.Y. 1991). After all, “[i]t makes little difference to the party victimized by the destruction of evidence whether that act was done willfully or negligently. The adverse inference provides the necessary mechanism for restoring the evidentiary balance.” *Id.*

Here, an adverse inference instruction—at least—is needed to restore the evidentiary balance. Plaintiffs have lost access to tens of thousands of documents, maybe more. It would be highly unfair for Ethicon to gain an advantage in defending thousands of cases by losing and destroying documents. The Court could tailor the instruction to the circumstances of each case, to avoid unfair prejudice to either side. Then the jury would decide whether to assign any importance to the missing information. If done properly, the instruction would not be “a

declaration of victory,” as Ethicon claims. The instruction would simply be a way to approximate the position that that parties would have occupied if Ethicon had met its obligations.

**C. Ethicon Should Not Be Allowed to Assert Affirmative Defenses Where it Destroyed Key Evidence Relating to those Defenses**

Ethicon’s argument that Plaintiffs’ request to strike Ethicon’s affirmative defenses be denied because Plaintiffs “cannot establish that any of the lost information has anything to do with Ethicon’s defenses”<sup>56</sup> holds Plaintiffs to an impossible standard. “Courts must not hold the prejudiced party to too strict a standard of proof regarding the likely contents of the destroyed evidence, because doing so would allow parties who have destroyed evidence to profit from that destruction.” *DMAC LLC v. City of Peekskill*, No. 09 Civ. 5093, 2012 U.S. Dist. LEXIS 138605, \*12 (S.D.N.Y. Sept. 17, 2012) (quoting *Cedar Petrochemicals, Inc. v. Donghu Hangong Chem. Co. Ltd.*, 769 F. Supp.2d 269, 290 (S.D.N.Y. 2011)).<sup>57</sup> This is especially true where Ethicon bears the burden of showing how the Plaintiffs have *not* been prejudiced by the spoliation. *Fitzpatrick v. Am. Int'l Group, Inc.*, No. 10 Civ. 142, 2013 U.S. Dist. LEXIS 77741, \*41 (S.D.N.Y. May 29, 2013) (“The noncompliant party bears the burden to demonstrate that the other parties did not suffer any prejudice from the spoliation.”).

Plaintiffs have explained why Ethicon’s learned intermediary affirmative defense should be stricken, and a flimsy excuse that “medical device sales representatives typically do not maintain”<sup>58</sup> documents informing doctors about the risks of pelvic mesh (or offering that Plaintiffs could undertake the burdensome task of deposing every doctor who interacted with

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<sup>56</sup> Ethicon Br. at 32.

<sup>57</sup> See also *Mastr*, 2013 U.S. Dist. LEXIS 152441, at \*27 (“[The] burden is not an onerous one, lest the spoliator be permitted to profit from its destruction.”).

<sup>58</sup> *Id.*

Ethicon's sales representatives) does *not* excuse the failure to "maintain" these documents—especially when a litigation hold has been issued.<sup>59</sup> *In re Pradaxa*, 2013 U.S. Dist. LEXIS 173674, \*51-52 (failure to produce information from sales representatives' custodial files "ridiculous," and notes concerning sales representatives' meetings with physicians should have been produced because it was both relevant and discoverable). Without all of this information, Plaintiffs have an incomplete picture as to what Ethicon was telling physicians and patients.

Further, Ethicon's argument that Plaintiffs must prove that the missing documents show Ethicon "made fraudulent statements to plaintiffs that prevented them from filing suit in a timely manner"<sup>60</sup> is false. As Plaintiffs explained in their opening Brief, missing Ethicon documents demonstrate the deception of consumers—because Ethicon withheld information from consumers. Plaintiffs may establish Ethicon's fraudulent concealment by demonstrating that Ethicon voluntarily disclosed information, made a partial disclosure that conveyed a false impression, or failed to disclose new information which would have made an earlier representation misleading. *Ameristar Jet Charter, Inc. v. Signal Composites*, No. 98-cv-1360-M, 2001 U.S. Dist. LEXIS 14020, \*14 n. 4 (N.D. Tex. Sept. 7, 2001); *Bradford v. Vento*, 997 S.W.2d 713, 725 (Tex. App. 1999), *rev'd on other grounds*, 48 S.W.3d 749 (Tex. 2001)).

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<sup>59</sup> One sales representative testified that he handed over a binder of all of his physician call notes from 2004 through 2012 when he left the company. Ex. S, Mohler 6/7/13 Dep. at 17:24-18:9, 236:13-237:5. This contradicts Ethicon's representations to this Court that medical sales device representatives do not keep call notes regarding their interactions with physicians. It appears unlikely that the spoliation of physician call notes is limited to those of a single sales representative. Further, other documents bearing on these issues have not been produced: in-use dates and final versions of copy approved TTV-Retropubic IFU sheets prior to September 8, 2000, the TTV product brochure copy-approved on July 23, 2003 (no copies have been located), a final version of the TTV product brochure that was copy-approved on July 8, 2001 (only the copy approved draft version with mark-ups was produced), and a final version of the TTV product brochure copy-approved on August 26, 2000, among others. See Ex. T, TTV/SUI Patient Brochures Index and Production Bates Range Chart.

<sup>60</sup> Ethicon Br. at 33.

Plaintiffs are hampered in their ability to show that Ethicon provided physicians and patients with false or misleading information, given that much of what Ethicon provided through its brochures or its sales representatives has disappeared. Put simply: Plaintiffs have more than demonstrated how the documents relate to Ethicon's affirmative defenses. Ethicon should not be able to benefit from its destruction of documents by raising affirmative defenses that Plaintiffs could have refuted with the very documents Ethicon failed to preserve.

#### **D. Monetary Sanctions Should Not Supplant More Punitive Sanctions**

Ethicon dwells at length on its recent efforts to ensure compliance with litigation holds "going forward," hoping to convince the Court it has learned its lesson and sanctions are not warranted—or if they are, should be only monetary in nature.<sup>61</sup> Rule 37 expressly contemplates,<sup>62</sup> however, and courts do in fact impose monetary sanctions "in addition to" other sanctions.<sup>63</sup> Although monetary sanctions "compensate a party for the time and effort it was forced to expend in an effort to obtain discovery," they are "not normally given for punitive purposes." *Stream Cos., Inc. v. Windward Advertising*, No. 12-cv-4549, 2013 U.S. Dist. LEXIS 100319, \*19, 21 n.10 (E.D. Pa. July 17, 2013).<sup>64</sup> Here, Ethicon's complete disregard for its

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<sup>61</sup> See, e.g., Ethicon Br at 12, 34.

<sup>62</sup> Fed. R. Civ. P. 37 (b)(2)(C).

<sup>63</sup> See, e.g., *N.V.E., Inc. v. Palmeroni*, No. 06-5455 (ES), 2011 U.S. Dist. LEXIS 107600, \*22-24 (D.N.J. Sept. 21, 2011) (adverse inference and monetary sanctions); *TeleQuest Int'l Corp. v. Dedicated Bus. Sys.*, No. 06-5359 (PGS), 2009 U.S. Dist. LEXIS 19546, \*15-17 (D.N.J. Mar. 11, 2009) (same); *MOSAID Techs. Inc. v. Samsung Elecs., Co.*, 348 F. Supp. 332, 339 (same); *Advantacare Health Partners, LP v. Access IV*, No. C 03-04496 JF, 2004 U.S. Dist. LEXIS 16835, \*31 (N.D. Cal. Aug. 17, 2004) ("Defendants do not explain why the Court should order evidence sanctions instead of attorneys' fees, rather than in addition to them.").

<sup>64</sup> Sanctions can "also serve a remedial function by leveling the playing field[,] . . . a punitive function, by punishing the spoliator[,] . . . and a deterrent function, by sending a clear message that this type of behavior will not be tolerated." *MOSAID*, 348 F. Supp. 2d at 335.

preservation duties resulted in the destruction of significant evidence bearing on Plaintiffs' case.

Although Plaintiffs are no doubt entitled to compensation for their time spent uncovering Ethicon's spoliation and bringing this motion, to counter Ethicon's many years of gross neglect and other misconduct with only monetary sanctions would be a mere slap on the wrist.<sup>65</sup>

### **CONCLUSION**

For the foregoing reasons, Plaintiffs' motion should be granted.

Dated this 21<sup>st</sup> day of January, 2014.

Respectfully submitted,

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<sup>65</sup> See, e.g., *Hershberger v. Ethicon Endo-Surgery, Inc.*, No. 2:10-cv-008837 (S.D.W. Va. Oct. 4, 2011), Memorandum Opinion and Order, Dkt. No. 289 (Stanley, Magistrate Judge) (attached hereto as Ex. U) (ordering Ethicon Endo-Surgery to pay sanctions because their discovery practices led to plaintiffs filing "repeated additional discovery requests," deposing individuals "twice without sufficient documents having been disclosed prior to either deposition").

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*Plaintiffs' Steering Committee*

**CERTIFICATE OF SERVICE**

I hereby certify that I filed the foregoing memorandum on January 21, 2014, using the Court's CM-ECF filing system, thereby sending of the filing to all counsel of record for this matter. To the extent that any exhibits are confidential, place-holders have been filed electronically, and the exhibits have been e-mailed and/or sent by Federal Express to the Court and to counsel for Defendant Ethicon, Inc.

/s/ Edward A. Wallace  
Edward A. Wallace

## INDEX OF EXHIBITS

**EXHIBIT A:** Declaration of Vince Carnivale

**EXHIBIT B:** Descriptions of 22 Individuals with Incomplete Custodial Files

**EXHIBIT C:** May 22, 2003 Litigation Hold Notice, ETH.MESH.00875544

**EXHIBIT D:** Contradictory Testimony of James P. Mittenthal

**EXHIBIT E:** Mittenthal 5/14/13 Deposition Testimony; Excerpts

**EXHIBIT F:** CAPA07001 – Summary Report, ETH.MESH.09479227-47

**EXHIBIT G:** Mittenthal 9/25/13 Deposition Testimony, Excerpts

**EXHIBIT H:** Executive Summary: Medical, Regulatory and Quality Systems Diagnostic, ETH.MESH.04611734

**EXHIBIT I:** Mittenthal 8/13/13 Deposition Testimony, Excerpts

**EXHIBIT J:** Somerville New Hire and Transfer Employee Compliance Training, ETH.MESH.00619152

**EXHIBIT K:** Health Care Compliance, ETH.MESH.02087831

**EXHIBIT L:** Compliance, ETH.MESH.07946455, 65

**EXHIBIT M:** E-mail Correspondence, ETH.MESH.03750969

**EXHIBIT N:** Professional Education Meeting, ETH.MESH.01148645

**EXHIBIT O:** Rick Isenberg 11/6/13 Deposition Testimony, Excerpts

**EXHIBIT P:** Benjamin Watson 12/18/13 Letter to Andrew Faes

**EXHIBIT Q:** Benjamin Watson 12/20/13 Letter to Roger Cameron

**EXHIBIT R:** Roger Cameron 11/4/13 Letter to Benjamin Watson

**EXHIBIT S:** Troy Mohler Deposition Testimony, Excerpts

**EXHIBIT T:** TVT/SUI Patient Brochures Index and Production Bates Range Chart

**EXHIBIT U:** *Hershberger v. Ethicon Endo-Surgery, Inc.*, No. 2:10-cv-008837 (S.D.W. Va. Oct. 4, 2011), Memorandum Opinion and Order, Dkt. No. 289 (Stanley, Magistrate Judge)

**EXHIBIT V:** E-mail Correspondence, ETH.MESH.00594767